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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,812	06/29/2001	Thomas D. Madden	16303-008030	6998

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/896,812

Applicant(s)  
Madden

Examiner  
Gollamudi Kishore

Art Unit  
1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jan 13, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above, claim(s) 1-31 and 44-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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### **DETAILED ACTION**

**The request for the extension of time dated 1-13-03 is acknowledged.**

**1. Applicant's election with traverse of Group II (claims 32-63) in Paper No. 8 is acknowledged. The traversal is on the ground(s) that it would not place a substantially greater burden on the examiner. This is not found persuasive because the examiner is required to show a one way distinctiveness between the groups and it has been done so by the examiner.**

**The requirement is still deemed proper and is therefore made FINAL.**

**In response to the species election requirement, applicant elects a composition without empty liposomes. Therefore, the claims included in the prosecution are 32-43.**

### ***Claim Rejections - 35 USC § 102***

**2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

**(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

**3. Claims 32-35 and 39-41 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/13816 (Moynihan).**

**WO discloses liposomal formulations containing various camptothecins in a precipitated form. The drug-lipid ratios taught by WO appear to fall within the claimed**

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ratios (note the abstract, page 8, line 8 through page 11, line 15; page 12, lines 1-7; Examples 3 and 4 and claims).

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or  
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

4. Claims 32, 36 and 38-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Kirpotin (6,110,491).

Kirpotin discloses liposomal compositions wherein the active agent is in a precipitated form. The active agent can be any compound with ionizable groups. The active agents taught by Kirpotin are antineoplastic agents, doxorubicin, vincristine, vinblastin and others. The liposomes are made of various phospholipids or sphingomyelin and include cholesterol. The lipid-drug ratios appear to fall within the claimed ratios (note the abstract, col. 4, line 54 through col. 6, line 18; col. 9, lines 22-67; Examples and claims).

#### *Claim Rejections - 35 USC § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented

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**and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.**

**6. Claims 37 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/13816 cited above.**

**The teachings of WO have been discussed above. As pointed out, the lipid-drug ratios appear to fall within the claimed ratios (note the abstract, col. 4, line 54 through col. 6, line 18; col. 9, lines 22-67; Examples and claims). Assuming that the ratios are different, it is deemed obvious to one of ordinary skill in the art to vary the amounts of the active agents from the guidance provided by Kirpotin to obtain the best possible results.**

**7. Claims 37 and 39-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kirpotin cited above.**

**Kirpotin as pointed out above discloses liposomal compositions wherein the active agent is in a precipitated form. The active agent can be any compound with ionizable groups. The active agents taught by Kirpotin are antineoplastic agents, doxorubicin, vincristine, vinblastin and others. The liposomes are made of various phospholipids or sphingomyelin and include cholesterol. The lipid-drug ratios appear to fall within the claimed ratios (note the abstract, col. 4, line 54 through col. 6, line 18; col. 9, lines 22-67; Examples and claims). Assuming that the ratios are different, it is deemed obvious to one of ordinary skill in the art to vary the amounts of the active agents from the guidance provided by Kirpotin to obtain the best possible results. Kirpotin does not provide specific**

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examples using sphingomyelin as the amphiphilic lipid for the formation of the liposomes. However, as pointed out above, Kirpotin discloses that this lipid can be used for the formation of the liposomes and therefore, its use would have been obvious to one of ordinary skill in the art if this lipid is desired. Although Kirpotin does not specifically teach the neoplastic agents such as camptothecins, since he suggests the applicability of the system to ionizable drugs, it would have been obvious to one of ordinary skill in the art to use any drug including camptothecins since the principle of loading is the same.

8. Claims 37 and 39-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kirpotin cited above, further in view of Slater (6,355,268).

The teachings of Kirpotin have been discussed above. As pointed out above, what is lacking are the specific teachings of camptothecins as the neoplastic drugs.

Slater teaches liposomal formulations and a method of loading various camptothecins by using ion gradients (note the abstract, col. 10, line 10 through col. 12, line 56 and Examples).

The use of camptothecins as the anti-neoplastic agents in the liposomal compositions of Kirpotin would have been obvious to one of ordinary skill in the art since Slater shows that these drugs are ionic and can be loading using gradients just as in Kirpotin. One of ordinary skill in the art would expect at least similar loading of camptothecins in Kirpotin.

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**9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.**

**The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.**

**If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.**

**Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].**

**All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.**

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**Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.**



**Gollamudi S. Kishore, Ph. D**

**Primary Examiner**

**Group 1600**

*gsk*

**April 3, 2003**